DEPARTMENT OF HEALTH AND HUMAN SERVICES

9 1227d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 2, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Reference: Warning Letter SEA 01-52

Inspection ID: 1293040008

Ken Noakes, Radiology Supervisor
Lourdes Medical Center
520 North Fourth Avenue
P.O. Box 2568
Pasco, Washington 99302-2568

WARNING LETTER

Dear Mr. Noakes:

We are writing to you because on April 27, 2001, a representative of the State of Washington, Kelly Cameron, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

1. Phantom QC records were missing for at least 4 weeks for unit 1, [redacted] Mammography room.

2. Processor QC records in the month of January 2001 were missing for at least 30% of operating days, for processor [redacted], room DARKROOM.

3. Processor QC records were missing at least 5 consecutive days in the month of January 2001 for processor [redacted], room DARKROOM .

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

In addition, you should address the Level 2 finding which was listed on the inspection report. That level 2 finding was:

3. The facility does not have adequate written procedures for collecting and resolving consumer complaints and did not follow them when required.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: patient names or identification should be deleted from any copies submitted).*

Please submit your response to U.S. Food and Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law.

You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

Sincerely,

David P. Hajduk for
Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.

CC: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Kelly Cameron
State of Washington
2409 West Albany
Kennewick, Washington 99336